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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/744,350

05/22/2001

Francis X. Ignatious

00537-181002

5160

7590

11/14/2002

Brian R Morrill  
Biomeasure Incorporated  
27 Maple Street  
Milford, MA 01757

EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 11/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**09/744,350**

Applicant(s)  
**Ignatious**

Examiner  
**Michael Borin**

Art Unit  
**1631**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Aug 21, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 17-48 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 17-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

In response to restriction requirement filed 8/21/02, applicant requests to replace restriction requirement with lack of unity request because the instant application is a national stage of PCT International application, and, accordingly, the restriction requirement is not proper<sup>1</sup>. Examiner agrees that unity of invention practice, rather than restriction practice, is applicable in the instant case, and submits lack of unity requirement as requested by applicant. The previous restriction requirement is hereby vacated.

#### ***Lack of unity requirement***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

- I. Claims 17-29, drawn to first method of making of polymer microspheres.
- II. Claims 33-45, drawn to second method of making of polymer microspheres.
- III. Claims 30-32,46-48, drawn to polymer microspheres.

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<sup>1</sup>It is not clear, why applicant addresses restriction requirement which is asserted to be improper.

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The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Each of the Groups I, II claim a distinct and separate method. Method of Group I, does not require anionic counterion, as in method of Group II. Conversely, method of Group II does not require complexing peptide salt with a polyester, as required by method of Group I. The methods do not share a special technical feature because each method contains specific and unique method step which is not shared by another method, and methods do not rely upon each other for their ultimate use. As for the only common feature, the steps of suspension in organic solvent, dispersing in the presence of surfactant, and evaporating the organic surfactant, these steps are not novel as addressed in the International Search Report with the reference to document D1(US 5,444,832). Thus, groups I-II do not share a corresponding special technical feature.

As for the claims 30-32,46-48, drawn to polymer microspheres, the claims are in product-by-process format, and as such, it is the novelty and patentability of the instantly claimed product that need to be established and not that of the recited process steps. A product encompassed by said claims is not a special technical feature linking Group III and Group I or II, because a polymer microspheres obtained

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by a variety of methods are well known. See, e.g., document D1, mentioned in the Preliminary search Report.

### **Species Requirement**

The claims of the Groups are individually or dependently directed to a plurality of disclosed patentably distinct species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The claims of Groups are individually or dependently directed to a plurality of disclosed patentably distinct species of peptides (Groups I-III), surfactants (Groups I-II), polymers (groups I, II), polyesters (Group I), anionic counterions (Group II). For the purposes of initial examination on merits applicant is required to elect a single disclosed species of each for

I) one of the peptides or proteins, such as those listed in pages 8-13 specification; see also claims 25-29, for example.

II) one of polymers, such as those listed in claims 29, 45;

III) one of surfactants, such as those listed in claim 22;

IV) one of polyesters, such as those listed in claims 18;

V) one of anionic counterions, such as listed in claim 34.

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The species are distinct because of the difference in their physico-chemical characteristics and thus the difference in the conditions for precipitation, suspending, and/or complex forming.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

To be complete, a response to the election of species requirement should include a proper election along with a listing of all claims readable thereon, including any claims subsequently added. MPEP 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are

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unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

November 12, 2002

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.